This amendment: Response to Clinical Recommendation.
Date of original submission: 31 October 2014

Professional information for SINUTAB NASAL SPRAY

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

Sinutab Nasal Spray 0,1 % *w/v* solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 mL solution contains 1 mg Xylometazoline hydrochloride (0,1 % *w/v*).

Excipients with known effect:

Preservative: Benzalkonium chloride 0,02 % *w/v*

For the full list of excipients, see section 6 .1.

3. PHARMACEUTICAL FORM

Nasal spray, solution.

A clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Sinutab Nasal Spray is indicated for relief of nasal congestion accompanying hay fever, allergic rhinitis, colds and sinusitis.

4.2 Posology and method of administration

Adults and children over 12 years of age:

One spray into each nostril 2 – 3 times a day, as required.

(Maximum daily dose: 3 sprays).

Children under 12 years of age: Not recommended.

Do not use for more than 7 days. Do not exceed recommended dosage.

Method of administration

To use:

1. Remove the plastic cap from the nozzle.
2. On first use, press the plunger downwards, and release until a single spray is delivered.
3. Hold the bottle upright and place nozzle into one nostril. Depress the plunger and at the same time breathe in through your nose. Release the plunger and remove nozzle from the nostril. Repeat this procedure for the other nostril.
4. To keep clean, wipe the nozzle and replace the plastic cap after use.

4.3 Contraindications

- Hypersensitivity to xylometazoline hydrochloride or to any of the other ingredients (see section 6.1).
- Contraindicated in children under 12 years of age.
- The prolonged use of vasoconstrictor medicines is not indicated in cases of chronic rhinitis.
- Not to be used with antihypertensive medicines of the adrenergic neuron blocking type or monoamine oxidase inhibitors (MAOIs) or within 10 days of their discontinuation.
- Patients with trans-sphenoidal hypophysectomy or surgery exposing the dura mater.

4.4 Special warnings and precautions for use

Sinutab Nasal Spray is intended for short-term use only. Prolonged use of decongestants may lead to reactive hyperaemia, with increased nasal congestion and obstruction. This may lead to repeated or even continuous use of the Sinutab Nasal Spray by the patient (see section 4.8).

Sinutab Nasal Spray should be used with caution in patients showing a strong reaction to sympathomimetic medicines, as evidenced by signs of insomnia, dizziness. etc.
Sinutab Nasal Spray should be used with caution in patients with hypertension, cardiovascular disease, hyperthyroidism, narrow angle glaucoma or diabetes mellitus.
Patients should be instructed to discontinue use and consult a physician if symptoms persist or worsen, or if new symptoms occur.

Sinutab Nasal Spray contains preservatives

Sinutab Nasal Spray contains benzalkonium chloride. Long-term use may cause oedema of the nasal mucosa.

4.5 Interaction with other medicines and other forms of interaction

As for all sympathomimetics, a reinforcement of the systemic effects of xylometazoline, as in Sinutab Nasal Spray, by concomitant use of monoamine oxidase inhibitors (MOAIs), tricyclic or tetracyclic antidepressants, cannot be excluded, especially in case of overdose.

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Sinutab Nasal Spray in pregnancy has not been established. No foetal toxicity or fertility studies have been carried out in animals.

Lactation

No evidence of any adverse effect on the breastfed infant. However, it is unknown whether xylometazoline or its metabolites are excreted in human milk, therefore Sinutab Nasal Spray should only be used on the advice of a doctor while breastfeeding.

Fertility

No data available.

4.7 Effects on ability to drive and use machines

Sinutab Nasal Spray can cause side effects, such as drowsiness. Caution is advised before driving a vehicle or operating machinery until the effects of Sinutab Nasal Spray are known.

4.8 Undesirable effects

Immune system disorders:

Frequency unknown: hypersensitivity

Psychiatric disorders:

Frequency unknown: insomnia, somnolence

Nervous system disorders:

Less frequent: burning sensation mucosal

Frequency unknown: headache

Eye disorders:

Frequency unknown: transient visual disturbance

Cardiac disorders:

Frequency unknown: palpitations

Systemic cardiovascular effects have occurred, and this should be kept in mind when giving Sinutab Nasal Spray to people with cardiovascular disease.

Respiratory, thoracic and mediastinal disorders:

Less frequent: nasal dryness, local irritation

Frequency unknown: sneezing

Gastrointestinal disorders:

Frequency unknown: nausea

General disorders and administration site conditions:

Less frequent: rebound effect.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of Sinutab Nasal Spray is important. It allows continued monitoring of the benefit/risk balance of Sinutab Nasal Spray. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9 Overdose

Overdosage or accidental oral administration may cause hypertension, nausea, vomiting, headache, delirium, muscle twitching, epileptiform convulsions, depression of the central nervous system and marked reduction in body temperature and symptoms of drowsiness and coma, particularly in children. There is no specific treatment. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A16.1 Nasal decongestants

Pharmacotherapeutic group: Decongestants for topical use, sympathomimetics, plain

ATC code: R01AA07.

Xylometazoline is a sympathomimetic amine of the imidazoline class with a marked alpha-adrenergic activity. Xylometazoline has a vasoconstrictive effect which produces decongestion of mucous membranes when administered locally thereby improving nasal breathing and discharge of secretion.

When used topically as a nasal decongestant, xylometazoline acts rapidly and provides long-lasting relief.

Onset of action is usually observed within minutes, the decongestant effect being prolonged and lasting for up to 10 hours.

5.2 Pharmacokinetic properties

Absorption

When used and dosed correctly, the absorption of topically applied xylometazoline into the systemic circulation is generally negligible.

No information on distribution, metabolism, and excretion of xylometazoline in humans are available.

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride;

Disodium phosphate dihydrate (for pH adjustment);

Disodium edetate (E385);

Purified water;

Sorbitol (E420);

Sodium chloride;

Sodium dihydrogen phosphate dihydrate (for pH adjustment).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Store at or below 25 ºC.

6.4 Special precautions for storage

Store in a cool place.

Protect from light and keep container tightly closed.

Keep out of reach of children.

6.5 Nature and contents of container

Available in 10 mL and 15 mL bottles with metered-dose spray pump.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

8. REGISTRATION NUMBER

P/16.1/184

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/07/1982

10. DATE OF REVISION OF THE TEXT

13 March 2022

EXPORT REGISTRATION DETAILS:

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Kenya: H2011/20658/028

Namibia: 06/16.1/0227

Zambia: 082/058 P

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